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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/075,970

02/14/2002

Michael Helmus

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/075,970	Applicant(s) HELMUS, MICHAEL	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,9-21 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7,9-21 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 April 2008 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1, 3, 5-7, 9-21, 56, and 47 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17 and 18 recite the limitation "one or more additional coating layers" and "said additional coating layers." However, claim 1 fails to recite a first coating layer. Therefore, there is insufficient antecedent basis for this limitation in the claims. For examination purposes, the coating layer is interpreted as being the therapeutic agent layer recited in claim 16, since claim 18 recites that the

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coating layers comprise a therapeutic agent and claim 1 recites that the covering material "does not contain therein a therapeutic agent."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3, 5-7, 9-21, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (6,099,562) in view of Bolz (6,287,332 B1). Ding discloses an implantable medical device (see entire document) comprising a metallic inner core material (stent body), a biodegradable covering material (a polymer topcoat) completely covering the inner core and does not contain a therapeutic agent therein, and a plurality of coating layers containing a therapeutic agent (undercoats; for example, see column 6, lines 50-58, column 3, lines 60-65, column 2, lines 62-65, and column 4, lines 18-19). Ding fails to disclose the metallic inner core material is biodegradable.

Bolz discloses an implantable medical device, such as a bioresorbable stent (see entire document). Bolz teaches constructing the bioresorbable stent of degradable metallic materials. Bolz further teaches that stents of degradable metallic material combine the advantageous mechanical properties of metal stents (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.; for example, see column 3, lines 11-35) with the bioresorbability of polymer-based stents (for example, see column 2, lines 6-16). It is well within the general knowledge of one having ordinary skill in the art to use a known technique to improve similar devices in the same way. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Ding's metallic inner core from a biodegradable metallic material as taught by Bolz. Doing so would enable the stent to completely degrade over a certain period of time such that the patient would be able to avoid an unnecessary subsequent surgery to remove the stent once the stent is no longer needed.

The covering material of Ding's in view of Bolz device would substantially control the rate at which the inner core material becomes flexible upon contact with body fluids in that initially fluid will contact and degrade the biodegradable covering material prior to contacting the biodegradable inner core. The device is resorbed by the body within a period of time, thus the inner core material becomes decreasingly rigid, increasingly flexible, and increasingly biomechanically compatible with body tissue in contact with the device over time.

With further respect to claims 5, 7, 10, and 48, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the inner core and covering from the materials recited, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

With further respect to claims 11-14, Ding discloses the inner core material comprises a braided structure, but modifications may be made. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the inner core comprising the structures recited in claims 11, 12, and 14, since the applicant has not disclosed that the recited structures provide an advantage, are used for a particular purpose, or solve a stated problem over each other or any other structure and it appears the prior art structure, as also recited in claim 13, would perform equally well.

Claim 15 is being treated as a product by process limitation, in that “the tubular structure is micromachined or laser-cut” refers to the process of forming the tubular structure and not to the final product created. As set forth in MPEP 2113, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Examiner has evaluated the product

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claim without giving much weight to the method of its manufacture. Therefore, in this case, a stent as described above wherein the tubular body is formed by micromachining or laser-cutting is directed to the method of making the stent and not to the final product made.

With further respect to claims 19-21, Ding's in view of Bolz stent is capable of being used as claimed if one so desires.

With further respect to claims 46 and 47, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the stent to have adequate rigidity from about three to about six months and that is completely biodegradable within about six months to one year following implantation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
June 17, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773